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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 0404

Application Number: 09/894,924
Filing Date: June 28, 2001
Appellant(s): ASHKENAZI ET AL.

Jeffrey P. Kushan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 2, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The Appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Claim 85 is not rejected under 35 USC § 102, but rejected only under § 103. Note that the claims were renumbered under Rule 1.126 as indicated in the Advisory Action mailed 1/21/04 due to two different claims being numbered 77.

(7) Grouping of Claims

Appellant's brief includes a statement that all claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,885,800	EMERY ET AL.	3-1999
4,946,778	LADNER ET AL.	8-1990

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 14, 67, 69-72, 74-77 and 79-84 remain rejected under 35 U.S.C. § 102(e) as being anticipated by Emery et al. (US Patent 5,885,800, cited by applicants) as evidenced by US Patent 4,946,778

Emery et al. teach the TR4 polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application. Also taught are antibodies that bind TR4, including antibody fragments, monoclonals, polyclonals, chimeric, recombinant, and humanized antibodies, as well as methods of making the antibodies and antibody-producing host cells (col. 3, lines 22-27, and col. 10, line 58 to col. 11, line 28). Uses for such antibodies are listed and include affinity chromatography of TR4, treatment of TR4 related diseases including cancer. TR4 is disclosed as structurally related to tumor necrosis factor (TNF) receptors (*e.g.*, col. 6, lines 42-61) for which ligands, including FasL (Fas ligand) are known (col. 1, lines 31-40). The methods of making single chain recombinant antibodies are cited in Emery et al. (col. 11, line 13) as disclosed in US Patent 4,946,778. Also disclosed are TR4 polypeptide antagonists which are antibodies (col. 13, lines 22-23), which necessarily include antibodies that block the binding of TR4 with its ligand(s).

The disclosure of US Patent 4,946,778 includes techniques for production in *E. coli*, (*e.g.*, col. 35, lines 44-47) as well as yeast and mammalian host cells (col. 11, lines 12-18), and is provided as evidence of what is disclosed in Emery et al. and is not necessary for anticipation of the claimed invention.

Claim 85 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Emery et al. (US Patent 5,885,800, cited by applicants) and US Patent 4,946,778

Emery et al. teach the TR4 polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application. Also taught are antibodies that bind TR4 and well as methods of making the antibodies and antibody-producing (col. 3, lines 22-27, and col. 10, line 58 to col. 11, line 28). Uses for such antibodies include detection assays such as ELISA(col. 13, lines 13-39) as well as immunopreciptation (col. 13, lines 13-17). Emery does not does not teach antibodies with detectable labels.

US Patent 4,946,778 is cited by Emery et al. in col. 11, line 13, as teaching recombinant means of antibody production. US Patent 4,946,778 also teaches detectably labeled antibodies, including labeling with agents such as chemiluminescent labels (*e.g.*, col. 31, lines 59-63).

It would have been obvious to one of skill in the art at the time the invention was made to detectably label an antibody that bound TR4 using the teachings of US Patent 4,946,778 because Emery et al. teach the usefulness of such labeled antibodies in detection assays.

(11) Response to Argument

Appellant argues (pages 5-7) that Emery et al. fail to disclose any biological role, function or activity of the TR4 polypeptide because 1) there is only disclosure of tissue expression data and a structural relatedness to a large family of receptors, the TNF superfamily; 2) there is no identification of the ligand that binds TR4 and, 3) there are only speculative uses for treatment of a variety diverse diseases. The argument has been fully considered, but is not persuasive. As stated in a previous Office action (paper # 12, p. 3, beginning line 16), "An actual reduction to practice is not required for this to be an anticipatory reference.... According to MPEP § 2122, utility need not be disclosed in a reference. "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)." Further, as stated in MEPE § 2121.01, the courts have found that:

> "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention not novel' or anticipated' within section 102, the stated test is

whether a reference contains an enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). In the instant case, Emery et al. provides all that is necessary for the artisan of ordinary skill at the time the invention was made to make the claimed antibodies."

Appellant argues (p. 7) that because the disclosure of Emery et al. is scientifically deficient due to the lack of disclosed specific biological role, function or activity of TR4, the patent is legally insufficient to anticipate the claims. The argument has been fully considered, but is not persuasive. As discussed above, the Emery et al. disclosure is sufficient for anticipation of the claimed invention. Further, in *Noelle v Lederman*, 69 USPQ2d 1508 (CAFC 2004) at 1514-1515, the Court held that an antibody that binds antigen X (not withstanding a functional definition of the antibody) satisfies the requirements of 35 USC 112, first paragraph, as long as there is disclosed a "fully characterized antigen," either by its structure, formula, chemical name or physical properties...." Emery et al. has fully characterized TR4 by providing its complete amino acid sequence.

Appellant argues (paragraph bridging pages 7-8) that according to *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981), there must be sufficient disclosure under 35 USC 112, first paragraph, in a patent for the subject matter at issue, and that in *Alexander v Davis-Bournonville* cited by Appellant (second paragraph of p. 8), the subject matter must be able to support a claim to it. These cases are not on point for the issue at hand for the following reasons. First, a patent is presumed valid. Second, Emery et al. need not rely on benefit to any priority application for an effective filing date that satisfies the requirements under 35 USC 102(e). Third, in MPEP 2136.03, section IV, it is stated that, "In order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must (A) have a right of priority to the earlier date under 35 U.S.C. 120 and (B) support the invention claimed as required by 35 U.S.C. 112, first paragraph." The "claimed" refers to what is claimed in the application one is using the reference against, which is also

subject matter that could have been claimed in the priority application one is using as a reference. Any material that an applicant in a 102(e) priority reference could have claimed (i.e., is fully supported by the priority disclosure) can be used against another who later claims it. So even if *Wertheim* were applicable in this situation, which it is not since there is no issue of priority for the Emery patent, the disclosure of Emery et al. would still satisfy the requirements as supporting under 35 USC 112, first paragraph, claims to an antibody that binds TR4.

Appellants argue (pp. 9-10) that in light of the requirements for utility as set forth in the USPTO Utility Examination Guidelines (2001), Emery discloses no specific, substantial and credible utility for the presently claimed subject matter. The argument has been fully considered, but is not persuasive. As discussed above (p. 4) an anticipatory prior art reference need not disclose a utility, so the issue of whether TR4 of Emery et al. has utility is moot.

Appellants argue (pp. 11-12) that prior art must meet a different standard to qualify as under 102(e) compared to § 102(b), citing *In re* Bayer and arguing that a patent may serve as prior art under 102(b) where it may not support a rejection under 102(e). The argument has been fully considered, but is not persuasive. In *Bayer*, the requirements of 102(e) is quoted:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent.

It is maintained that Emery et al. meets this requirement and satisfies the requirements under 35 USC 112, first paragraph, for prior art by providing a "complete and adequate description of the thing claimed." (*Alexander Milburn*, cited by Appellant top of p. 12 of Brief).

Appellants argue that the rejection of claim 85 under 35 USC 103 should be withdrawn because, as discussed above, the Emery et al. patent is insufficient to anticipate the presently claimed antibodies. The argument has been fully considered, but is not persuasive. For the reasons set forth in the previous Office actions and as discussed above, the rejection is maintained.

In conclusion, the rejections are maintained because Emery et al. fully disclose the antigen and have an enabling disclosure for making the antigen and antibody.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Claire M. Kaufman
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April 29, 2004

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